

### AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions of claims in the application.

1. – 16. (Cancelled)

17. (Previously Presented) A sterile filterable dispersion comprising:

- (a) an aqueous dispersion medium;
- (b) fluticasone particles sufficiently small to pass through a 0.2 $\mu$ m filter, and have a phase selected from the group consisting of a crystalline phase, an amorphous phase, and a semi-crystalline phase; and
- (c) at least one surface stabilizer adsorbed on the surface of the fluticasone particles, wherein the dispersion is sterilized by filtration through a 0.2  $\mu$ m filter.

18. (Cancelled)

19. (Previously Presented) The sterile filterable fluticasone dispersion of claim 17, wherein the surface stabilizer is tyloxapol.

20. (Previously Presented) The sterile filterable fluticasone dispersion of claim 17, wherein at least 99.9% of the fluticasone particles have a particle size of less than 200 nm.

21. (Previously Presented) The sterile filterable fluticasone dispersion of claim 17, wherein at least 90% of the fluticasone particles have a particle size of less than 130 nm.

22. (Currently Amended) A sterile filterable fluticasone composition comprising:

- (a) particles of fluticasone or a salt thereof, wherein at least 99.9% of the fluticasone particles have a particle size of less than 200 nm; and
  - (b) tyloxapol as a surface stabilizer,
- wherein the composition is sterilized by filtration through a 0.2  $\mu$ m filter.

23. (Currently Amended) A nanoparticulate fluticasone composition comprising:  
(a) particles of fluticasone or a salt thereof, wherein the fluticasone particles have an effective average particle size of less than 150 nm; and  
(b) at least one surface stabilizer adsorbed on the surface of the fluticasone particles, wherein the composition ~~has been~~ is sterilized by ~~passing it~~ filtration through a 0.2µm filter.

24. (Previously Presented) The composition of claim 23, wherein the effective average particle size of the fluticasone particles is selected from the group consisting of less than 140 nm, less than 130 nm, less than 120 nm, less than 110 nm, less than 100 nm, less than 90 nm, less than 80 nm, less than 70 nm, less than 60 nm, and less than 50 nm.

25.-26. (Cancelled)

27. (Original) The composition of claim 23 formulated for administration selected from the group consisting of oral, pulmonary, rectal, ophthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

28. (Original) The composition of claim 23 further comprising one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

29. (Previously Presented) The composition of claim 28, wherein the fluticasone particles are present in the composition in an amount selected from the group consisting of from 99.5% to 0.001%, from 95% to 0.1%, and from 90% to 0.5%, by weight, based on the total combined dry weight of the fluticasone and at least one surface stabilizer, not including other excipients.

30. (Previously Presented) The composition of claim 28, wherein the at least one surface stabilizer is present in an amount selected from the group consisting of from 0.5% to 99.999%, from 5.0% to 99.9%, and from 10% to 99.5%, by weight, based on the total combined dry weight of the fluticasone and at least one surface stabilizer, not including other excipients.

31. (Original) The composition of claim 23, comprising at least two surface stabilizers.

32. (Original) The composition of claim 23, wherein the surface stabilizer is selected from the group consisting of an anionic surface stabilizer, a cationic surface stabilizer, a zwitterionic surface stabilizer, and an ionic surface stabilizer.

33. (Currently Amended) The composition of claim 32, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor ~~oil~~soil ~~derivatives~~, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl  $\beta$ -D-glucopyranoside; n-decyl  $\beta$ -D-maltopyranoside; n-dodecyl  $\beta$ -D-glucopyranoside; n-dodecyl  $\beta$ -D-maltoside; heptanoyl-N-methylglucamide; n-heptyl- $\beta$ -D-glucopyranoside; n-heptyl  $\beta$ -D-thioglucoside; n-hexyl  $\beta$ -D-glucopyranoside; nonanoyl-N-methylglucamide; n-nonyl  $\beta$ -D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl- $\beta$ -D-glucopyranoside; octyl  $\beta$ -D-thioglucopyranoside; lysozyme, PEG-derivatized phospholipid, PEG-derivatized cholesterol, PEG-derivatized cholesterol ~~derivative~~,

PEG-derivatized vitamin A, PEG-derivatized vitamin E, and random copolymers of vinyl acetate and vinyl pyrrolidone.

34. (Currently Amended) The composition of claim 32, wherein the at least one cationic surface stabilizer is selected from the group consisting of a polymer, a biopolymer, a polysaccharide, a cellulosic, an alginate, a nonpolymeric compound, a phospholipid, zwitterionic stabilizers, poly-n-methylpyridinium, anthryl pyridinium chloride, chitosan, polylysine, polyvinylimidazole, polybrene, polymethylmethacrylate trimethylammoniumbromide bromide (PMMTMABr), hexyldesyltrimethylammonium bromide (HDMAB), polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, 1,2 Dipalmitoyl-sn-Glycero-3-Phosphoethanolamine-N-[Amino(Polyethylene Glycol)2000] (sodium salt), Poly(2-methacryloxyethyl trimethylammonium bromide), poloxamines, lysozyme, alginic acid, carrageenan, and nonionic, high molecular weight, ~~watersoluble~~ water-soluble poly(ethylene oxide) polymers.

35. (Previously Presented) The composition of claim 32, wherein the at least one cationic surface stabilizer is selected from the group consisting of cationic lipids, sulfonium, phosphonium, quarternary ammonium compounds, stearyltrimethylammonium chloride, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium bromide, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium chloride, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium bromide, N-alkyl (C<sub>12-18</sub>)dimethylbenzyl ammonium chloride, N-alkyl (C<sub>14-18</sub>)dimethyl-benzyl ammonium chloride, N-

tetradecyldimethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C<sub>12</sub>, C<sub>15</sub>, C<sub>17</sub> trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyldimethylammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, polyquaternium 10, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearylalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, quaternized ammonium salt polymers, imidazoline, alkyl pyridinium salts, amines, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

36. (Currently Amended) The composition of claim 35, wherein the amine is selected from the group consisting of alkylamines, dialkylamines, alkanolamines, polyethylenepolyamines, N,N-dialkylaminoalkyl acrylates, vinyl pyridine, amine salts, lauryl amine acetate, stearyl amine acetate, alkylpyridinium salt, alkylimidazolium salt, amine oxides, and[[,]] imide azolinium salts.

37. (Original) The composition of claim 34, wherein the cationic surface stabilizer is a nonpolymeric compound selected from the group consisting of benzalkonium chloride, a

carbonium compound, a phosphonium compound, an oxonium compound, a halonium compound, a cationic organometallic compound, a quarternary phosphorous compound, a pyridinium compound, an anilinium compound, an ammonium compound, a hydroxylammonium compound, a primary ammonium compound, a secondary ammonium compound, a tertiary ammonium compound, behenalkonium chloride, benzethonium chloride, cetylpyridinium chloride, behentrimonium chloride, lauralkonium chloride, cetalkonium chloride, cetrimonium bromide, cetrimonium chloride, cethylamine hydrofluoride, chlorallylmethenamine chloride (Quaternium-15), distearyldimonium chloride (Quaternium-5), dodecyl dimethyl ethylbenzyl ammonium chloride(Quaternium-14), Quaternium-22, Quaternium-26, Quaternium-18 hectorite, dimethylaminoethylchloride hydrochloride, cysteine hydrochloride, diethanolammonium POE (10) oleyl ether phosphate, diethanolammonium POE (3)oleyl ether phosphate, tallow alkonium chloride, dimethyl dioctadecylammoniumbentonite, stearalkonium chloride, domiphen bromide, denatonium benzoate, myristalkonium chloride, laurtrimonium chloride, ethylenediamine dihydrochloride, guanidine hydrochloride, pyridoxine HCl, iofetamine hydrochloride, meglumine hydrochloride, methylbenzethonium chloride, myrtrimonium bromide, oleyltrimonium chloride, polyquaternium-1, procainehydrochloride, cocobetaine, stearalkonium bentonite, stearalkoniumhectonite, stearyl trihydroxyethyl propylenediamine dihydrofluoride, tallowtrimonium chloride, and hexadecyltrimethyl ammonium bromide.

38. (Original) The composition according to any of claims 32, 34, 35, 36, or 37, wherein the composition is bioadhesive.

39. (Currently Amended) A method of making a fluticasone composition comprising: contacting fluticasone or a salt thereof with at least one surface stabilizer for a time and under conditions sufficient to provide a particulate fluticasone composition comprising-particles of fluticasone having an effective average particle size of less than 900 150 nm-wherein ~~“effective average particle size of less than 900 nm” means that at least 50% of the particles of fluticasone or a salt thereof have a size of less than 900 nm;~~ and

passing the particulate fluticasone composition through a 0.2 $\mu$ m filter to sterilize the particulate fluticasone composition.

40. (Original) The method of claim 39, wherein said contacting comprises grinding.

41. (Original) The method of claim 40, wherein said grinding comprises wet grinding.

42. (Original) The method of claim 39, wherein said contacting comprises homogenizing.

43. (Original) The method of claim 39, wherein said contacting comprises:

- (a) dissolving the fluticasone particles in a solvent;
- (b) adding the resulting fluticasone solution to a solution comprising at least one surface stabilizer; and
- (c) precipitating the solubilized fluticasone having at least one surface stabilizer by the addition thereto of a non-solvent.

44. (Currently Amended) The method of claim 39, wherein the effective average particle size of the fluticasone particles is selected from the group consisting of ~~less than 800 nm, less than 700 nm, less than 600 nm, less than 500 nm, less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 150 nm,~~ less than 140 nm, less than 130 nm, less than 120 nm, less than 110 nm, less than 100 nm, less than 90 nm, less than 80 nm, less than 70 nm, less than 60 nm, and less than 50 nm.

45.-46. (Cancelled)

47. (Previously Presented) The method of claim 39, wherein the fluticasone has a phase selected from the group consisting of a crystalline phase, an amorphous phase, and a semi-crystalline phase.

48. (Previously Presented) The method of claim 39 further comprising formulating the particulate fluticasone composition into a dosage form suitable for administration to a patient, wherein the route of administration is selected from the group consisting of oral, pulmonary, rectal, ophthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

49. (Previously Presented) The method of claim 39, wherein the contacting step further comprises contacting the fluticasone with one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

50. (Previously Presented) The method of claim 49, wherein the fluticasone particles are present in the particulate fluticasone composition an amount selected from the group consisting of from 99.5% to 0.001%, from 95% to 0.1%, and from 90% to 0.5%, by weight, based on the total combined dry weight of the fluticasone particles and the at least one surface stabilizer, not including other excipients.

51. (Previously Presented) The method of claim 49, wherein the at least one surface stabilizer is present in the particulate fluticasone composition in an amount selected from the group consisting of from 0.5% to 99.999%, from 5.0% to 99.9%, and from 10% to 99.5%, by weight, based on the total combined dry weight of the fluticasone and the at least one surface stabilizer, not including other excipients.

52. (Original) The method of claim 39, wherein the fluticasone composition comprises at least two surface stabilizers.

53. (Original) The method of claim 39, wherein the surface stabilizer is selected from the group consisting of an anionic surface stabilizer, a cationic surface stabilizer, a zwitterionic surface stabilizer, and an ionic surface stabilizer.



54. (Currently Amended) The method of claim 53, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor ~~oil~~soil-derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl  $\beta$ -D-glucopyranoside; n-decyl  $\beta$ -D-maltopyranoside; n-dodecyl  $\beta$ -D-glucopyranoside; n-dodecyl  $\beta$ -D-maltoside; heptanoyl-N-methylglucamide; n-heptyl- $\beta$ -D-glucopyranoside; n-heptyl  $\beta$ -D-thioglucoside; n-hexyl  $\beta$ -D-glucopyranoside; nonanoyl-N-methylglucamide; n-noyl  $\beta$ -D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl- $\beta$ -D-glucopyranoside; octyl  $\beta$ -D-thioglucopyranoside; lysozyme, PEG-derivatized phospholipid, PEG-derivatized cholesterol, PEG-derivatized cholesterol-~~derivative~~, PEG-derivatized vitamin A, PEG-derivatized vitamin E, and random copolymers of vinyl acetate and vinyl pyrrolidone.

55. (Currently Amended) The method of claim 53, wherein the at least one cationic surface stabilizer is selected from the group consisting of a polymer, a biopolymer, a polysaccharide, a cellulosic, an alginate, a nonpolymeric compound, a phospholipid, zwitterionic stabilizers, poly-n-methylpyridinium, anthryl pyridinium chloride, chitosan, polylysine, polyvinylimidazole, polybrene, polymethylmethacrylate trimethylammoniumbromide bromide (PMMTMABr), hexyl-desyltrimethylammonium bromide (HDMAB), polyvinylpyrrolidone-2-

dimethylaminoethyl methacrylate dimethyl sulfate, 1,2 Dipalmitoyl-sn-Glycero-3-Phosphoethanolamine-N-[Amino(Polyethylene Glycol)2000] (sodium salt), Poly(2-methacryloxyethyl trimethylammonium bromide), poloxamines, lysozyme, alginic acid, carrageenan, and nonionic, high molecular weight, ~~watersoluble~~ water-soluble poly(ethylene oxide) polymers.

56. (Previously Presented) The method of claim 53, wherein the at least one cationic surface stabilizer is selected from the group consisting of cationic lipids, sulfonium, phosphonium, quarternary ammonium compounds, stearyltrimethylammonium chloride, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium bromide, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium chloride, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium bromide, N-alkyl (C<sub>12-18</sub>)dimethylbenzyl ammonium chloride, N-alkyl (C<sub>14-18</sub>)dimethyl-benzyl ammonium chloride, N-tetradecylidmethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride monohydrate, N-alkyl(C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl

ammonium bromide, C<sub>12</sub>, C<sub>15</sub>, C<sub>17</sub> trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyl dimethyl ammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethyl ammonium bromide, dodecyltriethyl ammonium bromide, tetradecyltrimethyl ammonium bromide, methyl trioctyl ammonium chloride, polyquaternium 10, tetrabutyl ammonium bromide, benzyl trimethyl ammonium bromide, choline esters, benzalkonium chloride, stearyl ammonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines quaternized ammonium salt polymers, imidazoline, alkyl pyridinium salts, amines, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

57. (Currently Amended) The method of claim 56, wherein the amine is selected from the group consisting of alkylamines, dialkylamines, alkanolamines, polyethylenepolyamines, N,N-dialkylaminoalkyl acrylates, vinyl pyridine, amine salts, lauryl amine acetate, stearyl amine acetate, alkylpyridinium salt, alkylimidazolium salt, amine oxides, and[[,]] imide azolinium salts.

58. (Original) The method of claim 55, wherein the cationic surface stabilizer is a nonpolymeric compound selected from the group consisting of benzalkonium chloride, a carbonium compound, a phosphonium compound, an oxonium compound, a halonium compound, a cationic organometallic compound, a quaternary phosphorous compound, a pyridinium compound, an anilinium compound, an ammonium compound, a hydroxyl ammonium compound, a primary ammonium compound, a secondary ammonium compound, a tertiary ammonium compound, behenalkonium chloride, benzethonium chloride, cetylpyridinium chloride, behentrimonium chloride, lauralkonium chloride, cetalkonium chloride, cetrimonium bromide, cetrimonium chloride, cethylamine hydrofluoride, chlorallylmethenamine chloride (Quaternium-15), distearyldimonium chloride (Quaternium-5), dodecyl dimethyl ethylbenzyl ammonium chloride(Quaternium-14), Quaternium-22, Quaternium-26, Quaternium-18 hectorite,

dimethylaminoethylchloride hydrochloride, cysteine hydrochloride, diethanolammonium POE (10) oleyl ether phosphate, diethanolammonium POE (3) oleyl ether phosphate, tallow alkonium chloride, dimethyl dioctadecylammoniumbentonite, stearalkonium chloride, domiphen bromide, denatonium benzoate, myristalkonium chloride, laurtrimonium chloride, ethylenediamine dihydrochloride, guanidine hydrochloride, pyridoxine HCl, iofetamine hydrochloride, meglumine hydrochloride, methylbenzethonium chloride, myrtrimonium bromide, oleyltrimonium chloride, polyquaternium-1, procaine hydrochloride, cocobetaine, stearalkonium bentonite, stearalkoniumhectonite, stearyl trihydroxyethyl propylenediamine dihydrofluoride, tallowtrimonium chloride, and hexadecyltrimethyl ammonium bromide.

59. (Original) The method according to any of claims 53, 55, 56, 57, or 58, wherein the fluticasone composition is bioadhesive.

60. (Currently Amended) A method of treating a subject in need of either symptomatic or prophylactic treatment with a sterile particulate fluticasone composition comprising the step of administering to the subject an effective amount of the sterile particulate fluticasone composition sterilized by passing the composition through a 0.2µm filter, wherein the sterile particulate fluticasone composition comprises particles of fluticasone or a salt thereof and at least one surface stabilizer, wherein the fluticasone particles have an effective average particle size of less than 900 150 nm, ~~wherein “effective average particle size of less than 900 nm” means that at least 50% of the particles of fluticasone or a salt thereof have a size of less than 900 nm.~~

61. (Currently Amended) The method of claim 60, wherein the effective average particle size of the fluticasone particles is selected from the group consisting of ~~less than 800 nm, less than 700 nm, less than 600 nm, less than 500 nm, less than 400 nm, less than 300 nm, less than 250 nm, less than 200 nm, less than 150 nm,~~ less than 140 nm, less than 130 nm, less than 120 nm, less than 110 nm, less than 100 nm, less than 90 nm, less than 80 nm, less than 70 nm, less than 60 nm, and less than 50 nm.

62.-63. (Cancelled)

64. (Previously Presented) The method of claim 60, wherein the subject has a condition selected from the group consisting of a respiratory related illness, inflammatory airways diseases, obstructive airways diseases, Whipple's disease, AIDS related pneumonia, asthma, emphysema, respiratory distress syndrome, chronic obstructive pulmonary disease, chronic bronchitis, cystic fibrosis, pneumonia, acquired immune deficiency syndrome related respiratory disorders, seasonal rhinitis, perennial rhinitis, seasonal allergic rhinitis, seasonal nonallergic rhinitis, perennial allergic rhinitis, perennial nonallergic rhinitis, and skin conditions treatable with topical corticosteroids.

65. (Original) The method of claim 64, wherein the subject has a condition selected from the group consisting of intrinsic (non-allergic) asthma, extrinsic (allergic) asthma, wheezy-infant syndrome, acute lung injury, acute respiratory distress syndrome, chronic obstructive pulmonary disease, chronic obstructive airways disease, chronic obstructive lung disease, chronic bronchitis, emphysema, bronchiectasis, exacerbation of airways hyperreactivity consequent to other drug therapy, and pneumoconiosis.

66. (Previously Presented) The method of claim 60, wherein the prophylactic efficacy of the treatment is evidenced by one or more characteristics selected from the group consisting of reduced frequency of symptomatic attack, reduced severity of symptomatic attack, improvement in lung function, improved airways hyperreactivity, and a reduced requirement for other symptomatic therapy.

67. (Original) The method of claim 60, wherein the subject is a human.

68. (Cancelled)

69. (Previously Presented) The method of claim 60, wherein the fluticasone has a phase selected from the group consisting of a crystalline phase, an amorphous phase and a semi-crystalline phase.

70. (Previously Presented) The method of claim 60, wherein the sterile particulate fluticasone composition is formulated into a dosage form suitable for administration to a patient, wherein said route of administration is selected from the group consisting of oral, pulmonary, rectal, ophthalmic, colonic, parenteral, intracisternal, intravaginal, intraperitoneal, local, buccal, nasal, and topical administration.

71. (Original) The method of claim 60, wherein the fluticasone composition further comprises one or more pharmaceutically acceptable excipients, carriers, or a combination thereof.

72. (Previously Presented) The method of claim 71, wherein the particulate fluticasone is present in the sterile particulate fluticasone composition in an amount selected from the group consisting of from 99.5% to 0.001%, from 95% to 0.1%, and from 90% to 0.5%, by weight, based on the total combined dry weight of the fluticasone and at least one surface stabilizer, not including other excipients.

73. (Previously Presented) The method of claim 71, wherein the at least one surface stabilizer is present in the sterile particulate fluticasone composition in an amount selected from the group consisting of from 0.5% to 99.999%, from 5.0% to 99.9%, and from 10% to 99.5%, by weight, based on the total combined dry weight of the fluticasone and at least one surface stabilizer, not including other excipients.

74. (Previously Presented) The method of claim 60, wherein the sterile particulate fluticasone composition comprises at least two surface stabilizers.

75. (Original) The method of claim 60, wherein the surface stabilizer is selected from the group consisting of an anionic surface stabilizer, a cationic surface stabilizer, a zwitterionic surface stabilizer, and an ionic surface stabilizer.

76. (Currently Amended) The method of claim 75, wherein the at least one surface stabilizer is selected from the group consisting of cetyl pyridinium chloride, gelatin, casein, phosphatides, dextran, glycerol, gum acacia, cholesterol, tragacanth, stearic acid, benzalkonium chloride, calcium stearate, glycerol monostearate, cetostearyl alcohol, cetomacrogol emulsifying wax, sorbitan esters, polyoxyethylene alkyl ethers, polyoxyethylene castor ~~oil~~oil derivatives, polyoxyethylene sorbitan fatty acid esters, polyethylene glycols, dodecyl trimethyl ammonium bromide, polyoxyethylene stearates, colloidal silicon dioxide, phosphates, sodium dodecylsulfate, carboxymethylcellulose calcium, hydroxypropyl celluloses, hypromellose, carboxymethylcellulose sodium, methylcellulose, hydroxyethylcellulose, hypromellose phthalate, noncrystalline cellulose, magnesium aluminum silicate, triethanolamine, polyvinyl alcohol, polyvinylpyrrolidone, 4-(1,1,3,3-tetramethylbutyl)-phenol polymer with ethylene oxide and formaldehyde, poloxamers; poloxamines, a charged phospholipid, dioctylsulfosuccinate, dialkylesters of sodium sulfosuccinic acid, sodium lauryl sulfate, alkyl aryl polyether sulfonates, mixtures of sucrose stearate and sucrose distearate, p-isononylphenoxypoly-(glycidol), decanoyl-N-methylglucamide; n-decyl  $\beta$ -D-glucopyranoside; n-decyl  $\beta$ -D-maltopyranoside; n-dodecyl  $\beta$ -D-glucopyranoside; n-dodecyl  $\beta$ -D-maltoside; heptanoyl-N-methylglucamide; n-heptyl- $\beta$ -D-glucopyranoside; n-heptyl  $\beta$ -D-thioglucoside; n-hexyl  $\beta$ -D-glucopyranoside; nonanoyl-N-methylglucamide; n-noyl  $\beta$ -D-glucopyranoside; octanoyl-N-methylglucamide; n-octyl- $\beta$ -D-glucopyranoside; octyl  $\beta$ -D-thioglucopyranoside; lysozyme, PEG-derivatized phospholipid, PEG-derivatized cholesterol, PEG-derivatized cholesterol ~~derivative~~, PEG-derivatized vitamin A, PEG-derivatized vitamin E, and random copolymers of vinyl acetate and vinyl pyrrolidone.

77. (Previously Presented) The method of claim 75, wherein the at least one cationic surface stabilizer is selected from the group consisting of a polymer, a biopolymer, a

polysaccharide, a cellulosic, an alginate, a nonpolymeric compound, a phospholipid, zwitterionic stabilizers, poly-n-methylpyridinium, anthryl pyridinium chloride, chitosan, polylysine, polyvinylimidazole, polybrene, polymethylmethacrylate trimethylammoniumbromide bromide (PMMTMABr), hexyl-desyltrimethylammonium bromide (HDMAB), polyvinylpyrrolidone-2-dimethylaminoethyl methacrylate dimethyl sulfate, 1,2 Dipalmitoyl-sn-Glycero-3-Phosphoethanolamine-N-[Amino(Polyethylene Glycol)2000] (sodium salt), Poly(2-methacryloxyethyl trimethylammonium bromide), poloxamines, lysozyme, alginic acid, carrageenan, and nonionic, high molecular weight, watersoluble poly(ethylene oxide) polymers.

78. (Previously Presented) The method of claim 75, wherein the at least one cationic surface stabilizer is selected from the group consisting of cationic lipids, sulfonium, phosphonium, quarternary ammonium compounds, stearyltrimethylammonium chloride, benzyl-di(2-chloroethyl)ethylammonium bromide, coconut trimethyl ammonium chloride, coconut trimethyl ammonium bromide, coconut methyl dihydroxyethyl ammonium chloride, coconut methyl dihydroxyethyl ammonium bromide, decyl triethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium chloride, decyl dimethyl hydroxyethyl ammonium bromide, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium chloride, C<sub>12-15</sub>dimethyl hydroxyethyl ammonium bromide, coconut dimethyl hydroxyethyl ammonium chloride, coconut dimethyl hydroxyethyl ammonium bromide, myristyl trimethyl ammonium methyl sulphate, lauryl dimethyl benzyl ammonium chloride, lauryl dimethyl benzyl ammonium bromide, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium chloride, lauryl dimethyl (ethenoxy)<sub>4</sub> ammonium bromide, N-alkyl (C<sub>12-18</sub>)dimethylbenzyl ammonium chloride, N-alkyl (C<sub>14-18</sub>)dimethyl-benzyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium chloride monohydrate, dimethyl didecyl ammonium chloride, N-alkyl and (C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, trimethylammonium halide, alkyl-trimethylammonium salts, dialkyl-dimethylammonium salts, lauryl trimethyl ammonium chloride, ethoxylated alkyamidoalkyldialkylammonium salt, an ethoxylated trialkyl ammonium salt, dialkylbenzene dialkylammonium chloride, N-didecyldimethyl ammonium chloride, N-tetradecyldimethylbenzyl ammonium, chloride



monohydrate, N-alkyl(C<sub>12-14</sub>) dimethyl 1-naphthylmethyl ammonium chloride, dodecyldimethylbenzyl ammonium chloride, dialkyl benzenealkyl ammonium chloride, lauryl trimethyl ammonium chloride, alkylbenzyl methyl ammonium chloride, alkyl benzyl dimethyl ammonium bromide, C<sub>12</sub>, C<sub>15</sub>, C<sub>17</sub> trimethyl ammonium bromides, dodecylbenzyl triethyl ammonium chloride, poly-diallyldimethylammonium chloride (DADMAC), dimethyl ammonium chlorides, alkyl dimethyl ammonium halogenides, tricetyl methyl ammonium chloride, decyltrimethylammonium bromide, dodecyltriethylammonium bromide, tetradecyltrimethylammonium bromide, methyl trioctylammonium chloride, polyquaternium 10, tetrabutylammonium bromide, benzyl trimethylammonium bromide, choline esters, benzalkonium chloride, stearylalkonium chloride compounds, cetyl pyridinium bromide, cetyl pyridinium chloride, halide salts of quaternized polyoxyethylalkylamines, quaternized ammonium salt polymers, imidazoline, alkyl pyridinium salts, amines, protonated quaternary acrylamides, methylated quaternary polymers, and cationic guar.

79. (Currently Amended) The method of claim 78, wherein the amine is selected from the group consisting of alkylamines, dialkylamines, alkanolamines, polyethylenepolyamines, N,N-dialkylaminoalkyl acrylates, vinyl pyridine, amine salts, lauryl amine acetate, stearyl amine acetate, alkylpyridinium salt, alkylimidazolium salt, amine oxides, and[[,]] imide azolinium salts.

80. (Original) The method of claim 77, wherein the cationic surface stabilizer is a nonpolymeric compound selected from the group consisting of benzalkonium chloride, a carbonium compound, a phosphonium compound, an oxonium compound, a halonium compound, a cationic organometallic compound, a quaternary phosphorous compound, a pyridinium compound, an anilinium compound, an ammonium compound, a hydroxylammonium compound, a primary ammonium compound, a secondary ammonium compound, a tertiary ammonium compound, behenalkonium chloride, benzethonium chloride, cetylpyridinium chloride, behentrimonium chloride, lauralkonium chloride, cetalkonium chloride, cetrimonium

bromide, cetrimonium chloride, cethylamine hydrofluoride, chlorallylmethenamine chloride (Quaternium-15), distearyldimonium chloride (Quaternium-5), dodecyl dimethyl ethylbenzyl ammonium chloride(Quaternium-14), Quaternium-22, Quaternium-26, Quaternium-18 hectorite, dimethylaminoethylchloride hydrochloride, cysteine hydrochloride, diethanolammonium POE (10) oleyl ether phosphate, diethanolammonium POE (3)oleyl ether phosphate, tallow alkonium chloride, dimethyl dioctadecylammoniumbentonite, stearalkonium chloride, domiphen bromide, denatonium benzoate, myristalkonium chloride, laurtrimonium chloride, ethylenediamine dihydrochloride, guanidine hydrochloride, pyridoxine HCl, iofetamine hydrochloride, meglumine hydrochloride, methylbenzethonium chloride, myrtrimonium bromide, oleyltrimonium chloride, polyquaternium-1, procainehydrochloride, cocobetaine, stearalkonium bentonite, stearalkoniumhectonite, stearyl trihydroxyethyl propylenediamine dihydrofluoride, tallowtrimonium chloride, and hexadecyltrimethyl ammonium bromide.

81. (Original) The method according to any of claims 75, 77, 78, 79, or 80, wherein the composition is bioadhesive.

82.–99. (Cancelled)